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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/466,035 12/17/99 SALLBERG M 930049.458C1

027476 HM12/1010  
CHIRON CORPORATION  
INTELLECTUAL PROPERTY - R440  
P.O. BOX 8097  
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EXAMINER

PARAS JR, P

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

**Office Action Summary**

Applicant(s)

09/466,035

Applicant(s)

SALLBERG ET AL.

Examiner

Peter Paras

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 July 2001.
- 2a) ☒ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 12, 13, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 12, 13, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Continued Prosecution Application***

The request filed on July 27, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/466,035 is acceptable and a CPA has been established. An action on the CPA follows.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 12-13, and 24-25 as originally filed, amended or newly added are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The previous rejection is maintained for the reasons of record advanced in the Office action mailed on 2/2/01 on pages 2-7.

Applicants have not provided any arguments in the amendment filed on July 27, 2001. Applicants have amended the claims to include the term "gene delivery vehicle".

In response, the Examiner maintains the rejection of record. Applicants have not provided any arguments to the rejections set forth in the Office action mailed on 2/2/01. The claim amendments do not address the enablement rejection of record. The prior rejection set forth the unpredictability of the art of gene therapy. See Marshall and

Verma on pages 4-5 of the Office action mailed on 2/2/01. The prior rejection also established the unpredictability of using alphavirus vector for transferring exogenous DNA *in vivo*. See Frolov, Ohno, and Garoff on pages 5-6 of the Office action mailed on 2/2/01. As Applicants have not provided any arguments to the enablement rejection of record and the claim amendments have not addressed the same rejections the standing rejection under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 12-13, and 24-25 as originally filed, amended or newly added are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The prior rejections of record are maintained for the reasons of record advanced in the Office action mailed on 2/2/01 on pages 7-8.

Applicants have amended the claims to recite "gene delivery vehicle". Applicants have not provided any arguments in response to the rejections of record.

In response, the Examiner has maintained the rejections of record as the prior rejections have not been addressed by amendment or argument. The standing rejections have been reiterated below for Applicant's convenience.

Claim 1 is incomplete. The claim as written does not provide a positive process step that relates back to the preamble of the claim, such that treatment is defined within

the claims as written. Furthermore, applicants' specification fails to define treatment such that the metes and bounds of the concept of treatment can be discerned.

Additionally, in claim 1, step (a), the term derived is indefinite. Derived tends to imply a lineage of development, however, this does not appear to be the context for which applicants are using the term. It is suggested that the term "isolated" be used instead of "derived" to clarify the claim.

Claim 1 is further indefinite, because it is unclear whether the immunogenic portion of an antigen administered in step (b) need to be the same immunogenic portion of antigen administered in step (a), or just one of a variety of immunogenic portions administered in step (a). In other words, step (a) recites the administration of "at least one immunogenic portion of an antigen", step (b) recites the administration of said immunogenic portion of step (a), however, step (a) can comprise numerous immunogenic portions. Thus, it is unclear if step (b) is the administration of all immunogenic portions of step (a) or whether it can be just one immunogenic portion. Clarification is necessary. Claims 2-5 and 11-12 depend from claim 1.

Claim 5 is indefinite because the phrase "said viral antigen" lacks antecedent basis in claim 3 from which it depends. It appears claim 5 is intended to depend from claim 4, rather than claim 3. Correction is necessary.

The addition of new claim 25 has necessitated the following new grounds of rejection under 35 U.S.C. 112, second paragraph:

Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites the limitation "The composition of claim 1" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 is a method claim and not a composition.

### **Conclusion**

No claims are allowed. **Claims 1-5, 12-13, and 24-25 are free of the prior art of record because the prior art of record does not teach or suggest a method of treatment comprising administration to a warm-blooded animal an alphavirus construct that directs the expression of an immunogenic portion of an HIV antigen and a protein which comprises the same immunogenic portion of an HIV antigen. The claims, however, are subject to other rejections. Also please note that claims 14-23 were cancelled upon election of group I filed on 12/27/00 (the pending claims). In view of such, it is not clear however, why Applicants have submitted amendments to claims 14, 17, 21 and 23.**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached at 703-305-6608. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Kay Pinkney whose telephone number is (703) 305-3553.

Peter Paras, Jr.

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